

# A clinical study on *Pandu Roga*, iron deficiency anemia, with *Trikatrayadi Lauha* suspension in children

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## ABSTRACT

**Context:** Nutritional iron deficiency is the most common cause of anemia in India. The nearest correlation of iron deficiency anemia (IDA) can be made with *Pandu Roga* in Ayurveda. As the IDA is a very common prevalent disease in the society and the side effects of oral allopathic iron preparations are very common, therefore to get a better alternative, an Ayurvedic herbomineral medicine, the *Trikatrayadi Lauha*, was subjected to a clinical trial in children suffering from IDA. **Aim:** Evaluation of safety and efficacy of the compound *Trikatrayadi Lauha* suspension in children with IDA. **Settings and Design:** Randomized, double-blind placebo-controlled clinical study. **Materials and Methods:** The study was conducted on 123 children of IDA for a period of 10 weeks. Clinical features and hematological parameters were documented before, during and after treatment. **Statistical Analysis Used:** Observations of the study were analyzed and findings were evaluated by using statistical methods (Student's *t* test) **Results:** The present study shows that the trial drug *Trikatrayadi Lauha* suspension is effective to improve clinical features and hematological parameters significantly. The medicine is effective to increase the hemoglobin level 1.94 g/dL (8.52 -10.46 g/dL,  $P < 0.001$ ) in 5 weeks and 3.33g/dL (8.52 -11.85g/dL,  $P < 0.001$ ) in 10 weeks. No adverse effect of the trial drug was observed during the study. **Conclusions:** The results suggest that *Trikatrayadi Lauha* is significantly effective in the management of IDA in children.

**Key words:** Anemia, hemoglobin, iron deficiency, *Pandu Roga*, serum ferritin

## INTRODUCTION

A prominent diagnostic feature of *Pandu roga* is the pallor on the skin which occurs due to the quantitative and qualitative deficiency of *raktu dhatu* (~blood tissue) caused either in the form of deficiency of hemoglobin and/ or red blood cells (RBCs). Considering *Panduta* (pallor) as the

predominant sign, the disease is termed as *Pandu Roga*. The nearest correlation of iron deficiency anemia (IDA) can be made with *Pandu Roga*, because of the predominance of *Panduta* or pallor in the whole body<sup>[1]</sup>

Iron deficiency is a very common nutritional disorder worldwide and is known to affect approximately one third of the global population. While its incidence in affluent countries is low, the incidence of IDA in India is very high. According to National Family Health Survey (NFHS) III data, the incidence of anemia in urban children is 71%, rural is 84%, and overall is 79%.<sup>[2]</sup> Nutritional iron deficiency is the most common cause of anemia in India.<sup>[3]</sup>

IDA is a very common disease prevalent in the society and side effects of oral allopathic iron preparations are very frequently encountered.<sup>[4]</sup> With the aim that herbomineral medicines may be effective to manage childhood IDA without any side effects, the present study was carried out to study the efficacy of an Ayurvedic herbomineral compound *Trikatrayadi Lauha* suspension with the application of modern parameters.


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## MATERIALS AND METHODS

### Study design

A randomized, double-blind placebo-controlled clinical study was conducted in children suffering from IDA.

### Selection of cases

For the study the patients having the clinical features of *Pandu Roga* (IDA) were selected.

### Inclusion criteria

- Patients of either sex from age 1 to 16 years
- Children with hemoglobin level less than 11 g/dL.
- Microcytic hypochromic anemia on peripheral blood smears (PBSs).

After obtaining written informed consent from parents, children of both sexes with hemoglobin level below normal range and PBS showing microcytosis and hypochromia were included.

### Exclusion criteria

- Blood Hb less than 6 g/dL
- Patient having occult blood positive on stool examination
- Any other type of anemia except IDA
- IDA with any associated severe complication.

### Discontinuation criteria

- Blood hemoglobin level becomes less than 5 g/dL during the course of treatment
- Any other acute illness
- Parents not willing to continue
- Any severe untoward effect

### Selection of drug

*Trikatrayadi Lauha* is an Ayurvedic herbo-mineral formulation quoted in *Bhaishajya Ratnavali* for the treatment of *Pandu Roga*.<sup>[22]</sup> The compound was modified to make it in suspension form for easy administration to children. Honey and ghee as mentioned in original text were not taken in suspension form of the trial drug. *Trikatrayadi Lauha* suspension was taken as trial drug for the present research study.

### Approval of institutional ethical committee

Institutional Ethics committee's approval was taken for the prospective, randomized, double-blind, placebo-controlled, parallel group clinical study.

### Procurement of the drug

Both the trial drug and the placebo were prepared in the attached Pharmacy of the institute. The trial drug was prepared in the form of suspension in order to enhance its palatability and for easy administration in children. Both

the trial drug and placebo were of similar physical character and were packed in similar types of packing.

### Contents of *Trikatrayadi Lauha* suspension (in each 15 mL)

Contents of *Trikatrayadi Lauha* suspension (in each 15 mL) are presented in Table 1.

### Analytical study of trial drug

The trial drug sample was subjected to various physiochemical analytical tests to evaluate the standards of drug. Analytical test reports of the trial drug *Trikatrayadi Lauha* are as follows—Nature of preparation—Colloidal suspension

Colour—Brownish red

Odour—Odourless

Taste—Sweet

pH—6.8

Viscosity—360 cPs @ 21°C

Specific gravity—1.3

Predicted shelf life (ASLT)—3 years 6 months

Microbial contamination tests, heavy metal residues, and pesticide residues were within the normal limits. The sample exhibited positive test for iron.

### Schedule of treatment

Deworming was done before drug therapy. Cases

**Table 1: Contents of *Trikatrayadi Lauha* suspension (in each 15 mL)**

Drugs	Latin name	Amount
<i>Mandura Bhasma</i>	Ferrosoferric oxide	240 mg
<i>Lauha Bhasma</i>	Ferrosoferric oxide	60 mg
<i>Amalaki</i>	<i>Emblica officinalis</i>	Each 15 mL syrup contains extract derived from 750 mg of each herbal ingredients (serial no. 3–11)
<i>Haritaki</i>	<i>Terminalia chebula</i>	
<i>Vibhitaki</i>	<i>Terminalia belerica</i>	
<i>Shunthi</i>	<i>Zingiber officinale</i>	
<i>Pippali</i>	<i>Piper longum</i>	
<i>Maricha</i>	<i>Piper nigrum</i>	
<i>Chitraka</i>	<i>Plumbago zeylanica</i>	
<i>Mustaka</i>	<i>Cyperus rotundus</i>	
<i>Vidanga</i>	<i>Embelia ribes</i>	
<i>Sharkara</i>	Sugar	Q.S. (66.67% w/v)
Suspending agent	Sodium carboxymethyl cellulose	100 mg/10 mL
Color	Chocolate brown	Q.S.
Flavor	Sweet orange	Q.S.
Preservatives	Sodium benzoate	0.1%
	Sodium methyl paraben	0.1%
	Sodium propyl paraben	0.01%
	Sodium propyl paraben	0.1%
	Citric acid	

registered for the study were randomly divided into 2 groups.

Group A—Patients included in this group were treated with TTLS 01 (trial drug).

Group B—Patients registered in this group were treated with TTLS 02 (placebo).

Form of trial drug and placebo: Suspension.

Dose of trial drug and placebo: 0.5 mL/kg body weight into 2 divided doses.

Duration of treatment: 10 weeks.

Diet—Normal diet was advised to all the cases according to age.

Follow-ups were done every 2 weeks.

Follow-up feedbacks (responses on treatment) were taken after 5 weeks and 10 weeks of treatment.

### Laboratory investigations

- Blood for total RBCs, WBCs count, DLC, Hb g%, erythrocyte sedimentation rate (ESR), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), peripheral blood smear (PBS)
- Serum ferritin level, serum iron level, total iron binding capacity (TIBC)
- Urine routine and microscopic examination.
- Stool routine and microscopic examination.

Investigations of the patients were done in the attached pathology and biochemistry department of the institute.

### Assessment criteria

The results of the clinical study were assessed on the basis of observations of clinical features and laboratory findings. The following parameters were mainly adopted for assessing the response of the treatment.

### Clinical assessment

The following clinical findings were assessed before, during, and after the treatment:

*Vaivarnata* (pallor), *Daurbalyata* (weakness), *Shrama* (fatigue), *Aruchi* (anorexia), *Kopana* or *Adhirata* (irritability), *Shwasa* (dyspnea), *Hridayaspandana* (palpitation), and *Shotha* (edema)

### Laboratory assessment

The following laboratory findings had been assessed before, during, and after treatment:

1) Total RBC count, 2) blood hemoglobin level, 3) PCV, 4) MCV, 5) MCH, 6) MCHC, 7) PBS, 8) ESR, 9) serum iron level, 10) TIBC, and 11) serum ferritin level

### Description of grades and its relation with grade points

For the purpose of statistical assessment of results some grades and grade points considering the severity of different clinical features, and laboratory findings have been used as follows:

### Grading of clinical features

G0 (grade point 0)—No clinical feature/symptom

G1 (grade point 1)—Mild clinical feature/symptom

G2 (grade point 2)—Moderate clinical feature/symptom

G3 (grade point 3)—Severe clinical feature/symptom

### Grading of blood hemoglobin level

G0—Hemoglobin level > 11g/dL

G1—Hemoglobin level 9.5 g/dL to <11g/dL

G2—Hemoglobin level 7.5 g/dL to <9.5g/dL

G3—Hemoglobin level 6 g/dL to <7.5g/dL

### Overall assessment of result

The results were assessed on the basis of observations of clinical features and laboratory findings before, during and after treatment.

Very Good—Improvement 75% and above

Good—Improvement 50% and above but <75%

Fair—Improvement 25% and above but <50%

Poor—No improvement or marginal improvement <25%

### Adverse effect evaluation criteria

To rule out the possible adverse effects of studied drug, clinical criteria were adopted and documented in Adverse Effect Evaluation Format during the course of the study in every 2 weeks follow-up.

### Analysis of data and use of statistical methods

Observations documented during the study were analyzed and findings were evaluated by using statistical methods (Student's *t* test) to establish the efficacy.

## OBSERVATIONS AND RESULTS

Total 123 children of *Pandu Roga* (IDA) were registered in the clinical study and randomly divided in two groups viz. Group A (Trial Group) and Group B (Placebo Group). Out of 123 cases, 107 patients completed the treatment course while 16 patients dropped out due to irregular follow up. In Group A (Trial Group) 61 patients were registered and 55 patients completed the treatment. In Group B (Placebo Group) 62 patients were registered and 52 patients completed the treatment.

On the observation of age wise distribution of 107 patients of *Pandu Roga*, 33.64% patients were found to be from both age groups, i.e. between the age group of 1–5 years

and between the age group of 5–9 years. The maximum number of patients in this study were from urban (47.67%) and urban slum (37.38%) areas, while the 14.95% belonged to rural areas. In this study, the maximum number of patients were from lower class, that is 43.93%, while 37.38% belonged to lower middle class of society. A maximum number of patients, that is 58.88 % were nonvegetarians, whereas the remaining 41.12% patients were vegetarians. The maximum number of (71.03%) children included in the study were having average/normal body weight and 28.97% children were underweight. The study shows that 56.07% patients were having *Vata-Pitta Prakriti* and 28.97% were of *Pitta-Kapha Prakriti*, whereas 14.96% of patients were having *Vata-Kapha Prakriti* implies the type of bodily constitution as per Ayurvedic philosophy. A majority, that is, 78.50% of the patients were having *mandagni* (~ low digestive capacity). The study shows maximum, that is 55.14% patients, were having *madhyam koshtba*, and 23.43% patients displayed *mridu and krura koshtba*. (The term *koshtba* implies the inherent condition of the digestive system. *Mridu koshtba* ~ highly sensitive to laxative substances, *Madhya koshtba* ~ moderately sensitive and *krura koshtba* ~ very less sensitivity to laxative substances.)

After treatment, the trial group showed 89.29% relief in pica, whereas the placebo group perceived 61.54% relief. The study shows that *Trikatrayadi Lauha* suspension can be considered to be effective for the correction of microcytic and hypochromic anemia.

All the patients were examined biweekly for evaluation of any adverse drug reaction. It was found that the drug “*Trikatrayadi Lauha* suspension” had no noticeable side effect. The drug was tolerated well and not a single patient exhibited any adverse symptom.

## DISCUSSION

Though every age group is susceptible to the affliction of *pandu roga*, it is more common in small children due to the intake of iron deficient diet or less iron content in diet. Families of poor income group are unable to afford proper diet and due to improper and imbalanced diet, children of those families may get the disease. As per the WHO report iron deficiency is most common among groups of low socioeconomic status.<sup>[5]</sup> The disease *Pandu Roga* is equally prevalent in both vegetarians and nonvegetarians. The disease is more prevalent in the children having the *Prakriti* dominant in *Pitta*. As *Pandu Roga* is *Pitta* dominant *tridoshaja vikara* (~ disease caused due to anomalous behaviour of all the three doshas) and undernutrition is commonly found in *Vata* dominant persons so probably this might be the reason of majority of patients being of *Vata-Pitta Prakriti* group in the

present study. *Mandagni* and *Madhyam koshtba* are observed in maximum patients. Consuming insufficient diet due to *Mandagni* leads to malnutrition, the root cause of disease. According to Ayurveda abnormal function of *Agni* is the root cause of all diseases. *Madhyam Koshtba* showing dominance of *Kapha* leads to improper digestion, which is the important cause of any disease. *Kapha Dosha* is predominant during childhood period and *kapha dosha* also plays an important role in the pathogenesis of the disease.

After 10 weeks treatment with the trial drug, highly significant improvement was observed in the clinical features of IDA with *P* value < 0.001. After 5 and 10 weeks of medication with *Trikatrayadi Lauha* suspension comparatively faster improvements were observed in the clinical features such as pallor, anorexia, weakness, fatigue, irritability, and so on [Table 2]. Clinical features of *pandu roga* (~IDA) are mainly due to quantitative and qualitative reduction of Hb and less oxygen supply in the tissues. 1 g% hemoglobin, when fully saturated, combines with 1.34 mL of oxygen, therefore, hemoglobin concentration is an index of oxygen carrying capacity of blood. With the trial drug therapy hemoglobin status improves, body tissues get adequate oxygen, body metabolism improves, and ultimately relief in clinical symptoms is observed.

The present clinical study shows the hematinic potential of *Trikatrayadi Lauha* suspension. It is evident that the treatment of iron deficiency anemia with *Trikatrayadi Lauha* suspension shows statistically significant increase of hematologic values, such as blood Hb%, total RBC, PCV, MCV, MCH, MCHC, and so on. Blood hemoglobin level was improved significantly with a mean increase of 1.94 g/dL in 5 weeks (8.52–10.46 g/dL, *P* < 0.001) and 3.33 g/dL in 10 weeks (8.52–11.85 g/dL, *P* < 0.001) [Figure 1]. After 10 weeks treatment in the trial group, Hb was increased by 39.10%, whereas in the placebo group Hb was increased by only 3.33%. A significant improvement in serum iron, TIBC and serum ferritin level was obtained. In placebo group improvements in the hematologic values were not satisfactory [Tables 3 and 4].

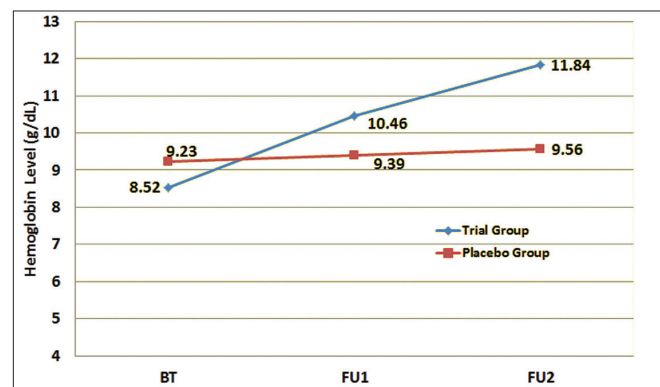


Figure 1: Comparing mean Hb levels between the two groups



**Table 2: Showing clinical recovery in patients of IDA treated with trial drug and placebo**

Parameters	Group	Treatment	Mean	D	Improvement %	Remarks
Vaivarnata (pallor)	Trial group	BT	2			
		FU1	0.86	1.15	57.27	*
		FU2	0.16	1.84	91.82	*
	Placebo group	BT	1.65			
		FU1	1.44	0.21	12.79	*
		FU2	1.26	0.39	23.26	*
Daurvalyata (weakness)	Trial group	BT	1.96			
		FU1	0.98	0.98	50.00	*
		FU2	0.22	1.75	88.89	*
	Placebo group	BT	2.02			
		FU1	1.42	0.60	29.52	*
		FU2	0.98	0.98	48.57	*
Shrama (fatigue)	Trial group	BT	1.98			
		FU1	1.01	0.96	48.62	*
		FU2	0.27	1.71	86.24	*
	Placebo group	BT	1.87			
		FU1	1.50	0.37	19.59	*
		FU2	1.12	0.75	40.21	*
Aruchi (anorexia)	Trial group	BT	1.62			
		FU1	0.53	1.09	67.42	*
		FU2	0.09	1.53	94.38	*
	Placebo group	BT	1.62			
		FU1	0.98	0.64	39.29	*
		FU2	0.67	0.94	58.33	*
Kopana/Adhirata (irritability)	Trial group	BT	0.91			
		FU1	0.49	0.42	46.00	*
		FU2	0.07	0.84	92.00	*
	Placebo group	BT	1.00			
		FU1	0.75	0.25	25	*
		FU2	0.60	0.40	40.39	*
Shwasa (dyspnea)	Trial group	BT	0.58			
		FU1	0.27	0.31	53.13	*
		FU2	0.07	0.51	87.50	*
	Placebo group	BT	0.65			
		FU1	0.60	0.06	8.82	
		FU2	0.54	0.12	17.65	
Hridayaspandana (palpitation)	Trial group	BT	0.80			
		FU1	0.47	0.33	40.91	*
		FU2	0.18	0.62	77.27	*
	Placebo group	BT	0.60			
		FU1	0.56	0.04	6.45	
		FU2	0.56	0.04	6.45	
Shotha (edema)	Trial group	BT	0.47			
		FU1	0.26	0.22	46.15	*
		FU2	0.06	0.40	88.46	*
	Placebo group	BT	0.48			
		FU1	0.42	0.06	12	
		FU2	0.32	0.15	32	

\*Highly significant with  $P$  value  $< 0.001$  BT, before treatment; FU-1= 1st followup; FU-2, 2nd followup.

The findings of the present study support the observations reported in other previous studies.<sup>[6,7]</sup>

*Trikatrayadi Lauha* suspension is more effective than placebo for the correction of eating disorder pica. Children especially those who are underfed and anemic are commonly affected with pica. As per modern pediatric text, iron deficiency is definitely responsible for pica in a large number of children and habit usually abates with iron therapy.<sup>[8]</sup>

The trial drug *Trikatrayadi Lauha* suspension was subjected to test for iron. As per analytical study reports the present trial drug contains 1.049 mg elemental iron per milliliter of the suspension. It contains mainly ferric iron and also ferrous iron, but in smaller quantities. Iron oxides, iron sulfide, and iron manganese hydroxide have been found to be present in the trial drug. Normally iron is recommended in the dose of 4–6 mg (elemental iron) per kg of body weight per day in divided doses. In the present clinical study the trial drug *Trikatrayadi*

**Table 3: Showing pattern of hematological changes in patients of IDA treated with trial drug and placebo**

Parameters	Group	Treatment	Mean	D	% Change	Remarks
Hemoglobin level (g/dL)	Trial group	BT	8.52			
		FU <sub>1</sub>	10.46	1.94	22.74	*
		FU <sub>2</sub>	11.84	3.33	39.10	*
	Placebo group	BT	9.23			
		FU <sub>1</sub>	9.39	0.15	1.73	
		FU <sub>2</sub>	9.56	0.32	3.53	
Total RBC count (mL/ $\mu$ L)	Trial group	BT	3.66			
		FU <sub>1</sub>	4.16	0.49	13.61	*
		FU <sub>2</sub>	4.46	0.79	21.64	*
	Placebo group	BT	3.78			
		FU <sub>1</sub>	3.80	0.02	0.71	
		FU <sub>2</sub>	3.82	0.04	1.12	
Packed cell volume (%)	Trial group	BT	27.45			
		FU <sub>1</sub>	32.06	4.61	16.79	*
		FU <sub>2</sub>	34.62	7.17	26.14	*
	Placebo group	BT	29.37			
		FU <sub>1</sub>	29.62	0.25	0.84	
		FU <sub>2</sub>	29.75	0.38	1.3	
Mean corpuscular volume (ft)	Trial group	BT	73.13			
		FU <sub>1</sub>	77.44	4.31	5.89	*
		FU <sub>2</sub>	79.68	6.55	8.95	*
	Placebo group	BT	77.29			
		FU <sub>1</sub>	77.37	0.07	0.10	
		FU <sub>2</sub>	77.50	0.21	0.27	
Mean corpuscular hemoglobin (pg)	Trial group	BT	22.66			
		FU <sub>1</sub>	25.18	2.52	11.13	*
		FU <sub>2</sub>	27.61	4.95	21.86	*
	Placebo group	BT	24.50			
		FU <sub>1</sub>	24.77	0.27	1.08	
		FU <sub>2</sub>	25.23	0.73	2.97	
Mean corpuscular hemoglobin concentration (g/dL)	Trial group	BT	30.58			
		FU <sub>1</sub>	32.50	1.92	6.27	*
		FU <sub>2</sub>	34.08	3.49	11.42	*
	Placebo group	BT	31.15			
		FU <sub>1</sub>	31.56	0.40	1.30	
		FU <sub>2</sub>	32.06	0.91	2.91	*
Erythrocyte sedimentation rate (mm 1 <sup>st</sup> hour)	Trial group	BT	27.42			
		FU <sub>1</sub>	21.87	5.55	20.23	*
		FU <sub>2</sub>	15.35	12.07	44.03	*
	Placebo group	BT	26.39			
		FU <sub>1</sub>	26.69	0.31	1.17	
		FU <sub>2</sub>	28.04	1.65	6.27	

\*Highly significant with  $P$  value < 0.001. BT, Before treatment; FU-1, 1<sup>st</sup> followup; FU-2, 2<sup>nd</sup> followup**Table 4: Showing effect of trial drug and placebo on serum iron level, TIBC and serum ferritin level**

Parameters	Group	BT	AT	D	% Change	Remarks
Serum iron level ( $\mu$ g/dL)	Trial group	24.86	67.33	42.47	170.89	*
	Placebo group	26.44	26.38	0.06	0.22	
Total iron binding capacity ( $\mu$ g/dL)	Trial group	436.86	327.20	109.66	25.10	*
	Placebo group	413.39	414.37	0.98	0.24	
Serum ferritin level (ng/mL)	Trial group	6.02	23.36	17.34	288.33	*
	Placebo group	6.93	7.02	0.09	1.31%	

\*Highly significant with  $P$  value < 0.001. BT, Before treatment; AT, After treatment

*Lauha* was administered in the dose of 0.5 mg/kg of body weight per day in two divided doses. Quantity of iron in the

administered dose of the trial drug was less with respect to normal recommendation. Absorption of ferrous form of iron

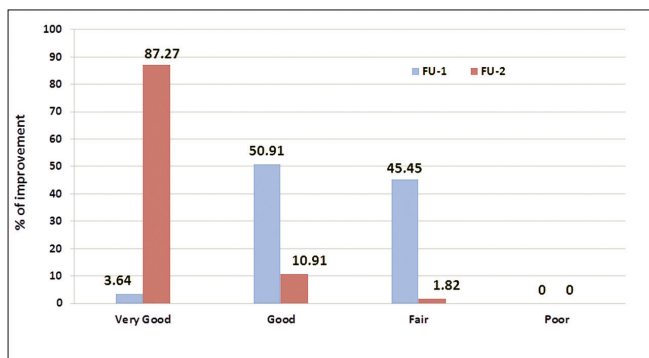
is more than ferric iron. But the present trial drug contains more amount of ferric iron than ferrous iron. Ferric iron can be converted in the presence of gastric acid by ferric reductase in the duodenal brush border to ferrous iron.<sup>[9]</sup>

*Trikatrayadi Lauha* suspension is an Ayurvedic herbomineral drug. The trial drug contains herbal drugs like *Triphala*, which is rejuvenative; *Trikatu*, which is an appetizer; and *Trimada*, which is digestive. Herbal ingredients in the trial drug may increase the bioavailability of *Mandura bhasma* and *lauha bhasma* which are important contents of the formulation. About 10% of iron in an average Indian diet is normally absorbed.<sup>[10]</sup> More is absorbed during deficiency states. Iron deficient state absorbs about 30% of dietary iron.<sup>[11]</sup> Although amount of iron in the administered dose of *Trikatrayadi Lauha* suspension is less and it contains iron mostly in less favorable ferric form but because of the herbal ingredients the trial drug may be equally effective in the management of iron deficiency anemia. During treatment significant improvement was observed in *Aruchi* (loss of appetite) in children. Appetizing property of the *Trikatrayadi Lauha* suspension might have helped in better tolerance, absorption, and metabolism of iron. The trial drug was in the form of suspension and sweet in taste. So the palatability of the trial drug *Trikatrayadi Lauha* suspension was good in children. No complaint of any uncomfortable feeling was

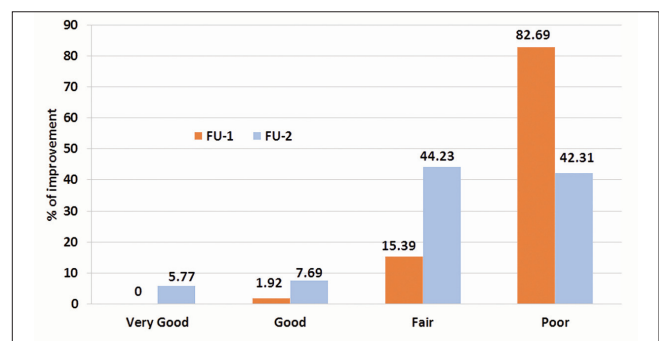
noticed during and after the drug administration. It does not produce gastric disturbances or constipation.

Effectiveness of *Haritaki*,<sup>[12]</sup> *Mandura Bhasma*,<sup>[13]</sup> and *Lauha Bhasma*<sup>[14,15]</sup> to increase blood hemoglobin level has been proved scientifically by previous research studies. *Amalaki* (*Emblica officinalis*) is richest source of Vitamin C, which helps in absorption of iron. Vitamin C reduces ferric iron to ferrous iron, which remains soluble even at neutral pH and is better absorbed. *Amalaki* enhances the production of RBCs and increases immunity in the body. *Pippali* is a proved drug to increase bioavailability. *Triphala* have *Anulomana* property and counteract the constipative effect of iron compounds like *Lauha Bhasma* and *Mandura Bhasma*. In a previous study a herbo-mineral compound *Panduhara Yoga* containing *Mandura Bhasma* 1 part and *Amalaki Churna* 10 parts in the dose of 110 mg/kg body weight in 2 divided doses, showed very good result in IDA in children. Hemoglobin level was improved with mean increase of 1.19 g/dL in 3 weeks ( $8.12 \pm 1.56$  g/dL to  $9.31 \pm 1.35$  g/dL,  $P < 0.001$ ) and 2.64 g/dL in 6 weeks ( $8.12 \pm 1.56$  g/dL to  $10.76 \pm 1.11$  g/dL,  $P < 0.001$ ).<sup>[16]</sup> Findings of the present study support the observations reported in these previous studies.

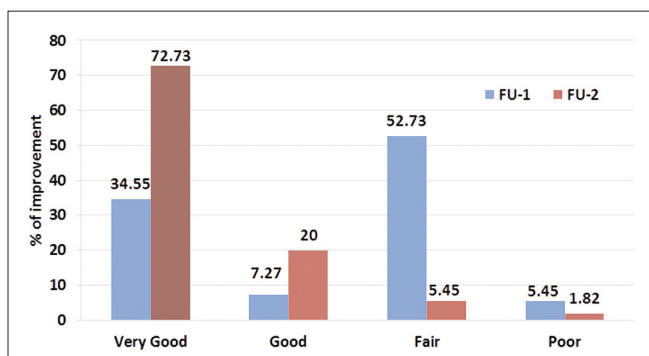
In previous experimental studies conducted on albino rats with ayurvedic herbomineral compounds like *lobhasava*<sup>[17]</sup> and *Navayas Lauha*<sup>[18]</sup> containing almost similar



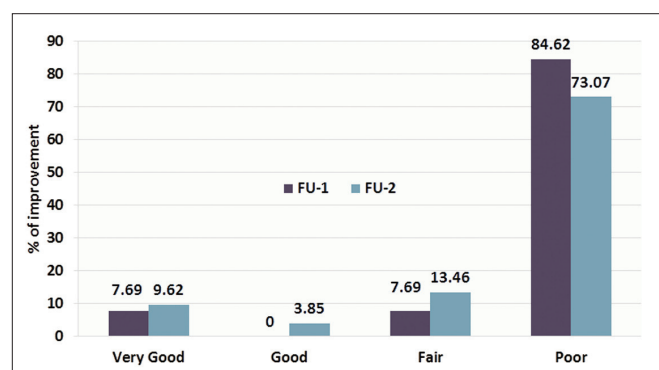
**Figure 2:** Overall effect of Trikatrayadi Lauha in the clinical features of iron deficiency anemia



**Figure 3:** Overall effect of placebo in the clinical features of iron deficiency anemia



**Figure 4:** Overall effect of Trikatrayadi Lauha to increase of blood Hb level



**Figure 5:** Overall effect of placebo to increase of blood Hb level

ingredients (*Lauha Bhasma*, *Triphala*, *Trikatu*, and *Trimada*, so on) such as *Trikatrayadi Lauha* suspension, no toxic (histopathological and biochemical) effect was observed. In another experimental study, *Lauha Bhasma* and *Mandura Bhasma* in 55 mg/kg dose (5 times the prescribed dose) for 60 days exhibited no serious toxic effects in Charles Foster albino rats.<sup>[19]</sup> On other experimental studies on albino rats, significant hematinic and cytoprotective activity of *Mandura Bhasma*<sup>[20]</sup> and *Lauha Bhasma*<sup>[14]</sup> have been proved.

Long-term treatment is needed for the treatment of IDA and *Trikatrayadi Lauha* suspension can be prescribed for long-term period without any adverse effect in children.

After 10 weeks treatment with *Trikatrayadi Lauha* suspension overall 87.27% children showed very good improvement on clinical features, whereas 72.73% children showed very good improvement on blood hemoglobin level [Figures 2 and 4]. Placebo has no specific role in the recovery of clinical features and to improve hematological parameters [Figures 3 and 5]. As per the observations and results found in the clinical study, the trial drug *Trikatrayadi Lauha* suspension is an effective medicine to manage the cases of *Pandu Roga*. The findings of the present study are consistent with previous studies,<sup>[21]</sup> reporting the Ayurvedic medicines may be more effective than conventional western treatment for the treatment of anemia.

## CONCLUSION

*Trikatrayadi Lauha* suspension has been subjected to a clinical study on children suffering from IDA. It contains iron (*Mandura Bhasma* and *Lauha Bhasma*) and herbal ingredients (*Triphala*, *Trikatu*, and *Trimada*). Herbal ingredients present in the trial drug may increase the bioavailability of iron. Hematinic action of *Trikatrayadi Lauha* suspension may be due to the presence of iron contents of good bioavailability. The present clinical study clearly indicates that the herbomineral formulation *Trikatrayadi Lauha* suspension is an effective, well-tolerated, and clinically safe formulation for the management of IDA in children.

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